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GUIDELINE

Guidelines of the Association of Polish Surgeons and the Polish Society of Surgical Oncology on the accreditation of healthcare centers providing cytoreductive surgery and HIPEC for primary and secondary peritoneal cancers

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ABSTRACT: Surgical interventions in patients with peritoneal metastases combined with hyperthermic intraperitoneal chemotherapy (HIPEC) and systemic treatment are becoming more common and, when applied to selected patient groups, they reach 5-year survival rates of 32–52%. Good clinical outcomes require experienced and well-equipped healthcare centers, experienced surgical team and adequate patient qualification process. As a result of the discussion on the need for evaluation of quality of care and treatment outcomes and at the request of the Peritoneal Cancer Section of the Polish Society of Surgical Oncology, accreditation standards have been developed and the Accreditation Committee has been established for healthcare centers providing cytoreductive surgery and HIPEC for the management of primary and secondary peritoneal cancers.

KEYWORDS: accreditation, cytoreduction, HIPEC, peritoneal cancer, quality of treatment

ABBREVIATIONS

APS – Association of Polish Surgeons
CC-0 – total cytoreduction
CC-1 – subtotal cytoreduction
CRS – cytoreductive surgery
EPIC – early postoperative intraperitoneal chemotherapy
HIPEC – hyperthermic intraperitoneal chemotherapy
ICU – intensive care unit
OS – overall survival
PCI – peritoneal cancer index
PM – peritoneal metastases
PMP – pseudomyxoma peritonei
PSSO – Polish Society of Surgical Oncology
RFS – recurrence-free survival

INTRODUCTION

Surgical resection in patients with peritoneal metastases combined with hyperthermic intraperitoneal chemotherapy (HIPEC) and systemic chemotherapy is becoming more common. Multiple studies have shown that the five-year survival can reach 32–52% providing appropriate patient selection [1–3]. Good outcomes depend on the local advancement of cancer in the peritoneum and the availability of radical cytoreduction.

Cytoreductive surgery (CRS) is an extensive and time-consuming procedure requiring an experienced operator. His or her experience, in turn, depends on the number of cytoreductive procedures previously performed, but also the experience in extensive abdominal surgeries is of utmost importance [3, 4]. Gaining experience by performing an increasing number of operations is called the

learning curve. It can be evaluated in different ways depending on the experience of the team and the operator, qualification for surgery and type of cancer. Equally important is the experience in pre- and postoperative management of patients following an extensive surgery [4].

All the above-listed issues affect the quality of the procedures, postoperative complication and mortality rates, and most important of all the overall survival (OS) and recurrence-free survival (RFS).

In Poland between 2009 and April 2020, there have been 1056 CRS/HIPEC procedures performed in seven centers, five of them performing more than 150 procedures per center. Since May 2019, CRS/HIPEC received reimbursement by the National Health Fund covering the costs of the operation, making it available for more widespread use in clinical centers specializing in surgical oncology, general surgery, gynecologic oncology and pediatric surgery.

As a result of the discussion on the need for evaluation of quality of care and treatment outcomes and at the request of the Peritoneal Cancer Section of the Polish Society of Surgical Oncology (PSSO), the joint Accreditation Committee has been established consisting of the members of the Association of Polish Surgeons (APS) and PSSO, which aims to evaluate all clinical centers providing cytoreductive surgery in terms of all aspects affecting the outcomes in patients with peritoneal metastases. For this purpose, the Registry of CRS/HIPEC Procedures has been created similar to the German [5] or French model [7], where each patient receiving CRS/HIPEC will be registered, which will be an obligatory requirement for accreditation.

INDICATIONS OF CYTOREDUCTIVE SURGERY AND HIPEC

CRS and HIPEC are recognized therapeutic options for peritoneal metastases (PM) of cancers including appendiceal malignancy tumors, peritoneal mesothelioma, pseudomyxoma peritonei and, in selected patients, peritoneal metastases of colorectal, gastric and ovarian cancer.

As far as pseudomyxoma peritonei, peritoneal mesothelioma, primary peritoneal malignancy and appendiceal cancer are concerned, cytoreductive surgery combined with HIPEC is the treatment of choice. In the presence of peritoneal metastases of colorectal cancer, CRS/HIPEC is performed in selected patients, where the Sugarbaker's Peritoneal Cancer Index (PCI) is less than 20 points, and no distant metastases are observed except for metachronic metastases in the liver (maximum three resectable lesions) and lungs (single resectable metachronic metastasis). In the case of peritoneal metastases of the gastric cancer, cytoreductive surgery is performed in very few patients, when the PCI score is less than 6 to 8 points.

In ovarian cancer patients, CRS/HIPEC is recommended in stage IIIc following neoadjuvant chemotherapy with positive response to systemic treatment.

In patients with other types of cancer with peritoneal metastases, or in patients with resectable peritoneal metastases (or in other organs), when the systemic treatment has been exhausted, it is acceptable to perform CRS/HIPEC under the following circumstances: no solid organ metastases, good general condition, expected improved health after surgery. The decision about possible or necessary surgery is made by the therapeutic team consisting of the surgeon, clinical oncologist, radiologist and pathologist.

Cytoreductive surgery or HIPEC should not be treatment on their own, but rather they should be a part of comprehensive multimodal treatment including systemic adjuvant and neoadjuvant therapy, surgery, ablation, targeted therapy, systemic immunotherapy, and other modalities in an individualized therapeutic regime for each patient. When the macroscopic resection of the tumor is possible, adjuvant therapy should have the curative intent.

The integral therapeutic intervention affecting the outcomes is improvement in nutritional status and respiratory function, as well as early assessment of the effect of comorbidities on treatment. The patient's biological state should influence the decision about qualification scheduling and extent of surgical intervention.

CRS/HIPEC is associated with complications relating mainly to the extent of surgery, reaching as high as 40% complication rate. The perioperative mortality is about 1 to 4%. Generally, the frequency and degree of complications associated with CRS/HIPEC is comparable to other extensive surgeries such as pancreaticoduodenectomy. For that reason, patient qualification, preoperative preparation, perioperative care and postoperative follow-up require that the surgical team is experienced in extensive and multi-organ surgeries, and have been subject to a comprehensive professional training in surgery of all abdominal regions. Cytoreduction often requires extensive organ and peritoneal resection, hypothermia as a result of prolonged operation or use of glucose solution (as solvent for oxaliplatin), which can lead to dangerous changes in osmolality affecting the central nervous system. For this reason, CRS/HIPEC must be performed in clinical centers with appropriate equipment as well as experienced surgeons and surgical team, which guarantee the best and safest treatment.

CONDITIONS FOR GOOD TREATMENT OUTCOMES AND LIMITATION OF POSTOPERATIVE COMPLICATIONS. LEARNING CURVE FOR CRS/HIPEC

The fundamental condition for successful CRS/HIPEC is to be able to provide complete (CC-0) or almost complete (CC-1) cytoreduction and to limit postoperative complications.

Bhatt et al. [7] analyzed the therapeutic outcomes of 384 patients with primary and secondary peritoneal cancer treated by 8 surgeons. Five of them had 10 to 15 years of experience in surgical oncology, two of them – 5 to 10 years, and one had more than 15 years of experience. Six out of the eight surgeons specialized in general surgery and surgical oncology, and two ouf of eight – in gastrointestinal surgery.

PCI ranged between 3 and 36, 18 on average. CC-0 was achieved in 86.7% of patients, CC-1 in 4.2%, and for the rest of the patients – CC-2/3. In 114/384 patients, additional EPIC (Early Postoperative Intraperitoneal Chemotherapy) with 5FU in 29% and Paclitaxel in 71%. Grade 3 to 5 complications according to the Clavien-Dindo Classification were observed in 27.3%. The 3-day perioperative mortality was 7.3%, the most common cause of death being

sepsis secondary to neutropenia. The complications included: neutropenia – 13%, anastomosis leak – 7.8%, ileus – 7.6%, respiratory failure – 4.7%, sepsis – 4.4%. Twenty-one out of thirty patients required reoperation. In conclusion, the authors believe that surgeon's experience in CRS/HIPEC is crucial to improve the outcomes.

On the other hand, Andreasson et al. [8] analyzed the therapeutic outcomes in 128 patients with pseudomyxoma peritonei (PMP) out of 307 patients undergoing CRS/HIPEC for peritoneal metastases. The group was divided into two subgroups: I – patients treated during the team's training (learning curve) – 73 patients, II – patients treated after the training ended. The radicality of R0/R1 in both groups was 48% vs 80% respectively (P = 0.0002). The intraoperative hemorrhage in Group I and II was 2000 mL vs 800 mL respectively (P < 0.0001), and the hospital stay was 18 days in Group I compared to 16 days in Group II (P = 0.016). The four-year survival was significantly greater in Group II compared do Group I – 80% vs 63% (P = 0.02). The RFS in Group I and II was 64% and 80% respectively, the difference being noticeable despite no statistical significance. The survival was affected by factors such as PCI and pathology result (MCP-L vs MCP-H). The stabilization of outcomes in PMP treatment was observed after 220 ± 10 procedures, which is a greater number of procedures necessary compared to other peritoneal cancers. It is caused by more advanced disease based on PCI score in patients qualified for surgery than e.g. in colorectal cancer, and as a result the extent of surgery is greater, which is directly related to the higher postoperative complication rate.

The learning curve should not only be limited to surgical skills (which are crucial for cytoreductive and multi-organ surgery), but also it should be applied to qualification process for CRS/HIPEC. The authors believe that the optimal stabilization of CRS for a given clinical center can be achieved after performing 200 procedures.

In their study [9], Chang et al. compared the outcomes of peritoneal cancer patients treated at the clinical center actively cooperating with a more experienced 'mentor' center. The study included 24 PMP patients with a mean PCI score of 20.3 (6 – 39), while 26 patients had peritoneal metastases from other locations (mainly colorectal cancer) with a mean PCI score of 8.7 (2–21). CC-0 was achieved in 80.8% of patients with peritoneal metastases of colorectal cancer, while CC-0 was 75% in PMP patients. The mean ICU stay was 5 days, while the mean total hospital stay was 14 days. No grade 3 or 4 complications or deaths were observed postoperatively. Grade 1 or 2 complications were present in 32% of patients, and 29 patients required blood transfusion, the number of administered units of packed red blood cells was greater in the colorectal cancer patients. CRS/HIPEC was a part of the complex treatment including diagnostic, qualification, preparation, surgical, oncologic and anesthesiologic procedures. All of them contributed to the outcome. In the authors' opinion, in order to achieve optimal and stable therapeutic outcome, including reduced perioperative complication rate and mortality, it is recommended to perform 90 to 180 procedures as the 'learning curve' at the clinical center. As shown by our results, the number of procedures of the learning curve can be lowered when the clinical center is monitored by an 'authorizing' institution with an appropriate experience in CRS/HIPEC.

In the literature, which analyzes the experience of the surgeon and the facility providing CRS/HIPEC, the study by Voron et al. has been widely cited [10]. As the main cause of perioperative complications the authors list the following: previous abdominal surgery aged over 60, local advancement in the peritoneum – CI over 12 points and more than 6 areas. Analyzing his results, Voron proposes that new centers starting with CRS/HIPEC should avoid risk factors, limit cytoreductive surgery to metastases of colorectal cancer, appendiceal cancer and ovarian cancer, excluding patients with pseudomyxoma or mesothelioma. CRS/HIPEC procedures should be monitored by fully trained surgeons. The authors state that it is crucial that the surgeon's experience is no less than 40 procedures in order to reach > 70% complete resection (CC-0) rate, and 140 procedures to achieve fully satisfactory results in terms of reducing complication rates, radical resection and improved outcomes.

In the study by Polanco et al. [11], the analysis covered the CRS /HIPEC treatment results in 370 patients with either appendiceal cancer (282), peritoneal mesothelioma (60) or gastric cancer (24) with peritoneal metastases. CC-0 was achieved in 84.2% of patients, and 60-day complication rate was 30% with perioperative mortality of 1.9%. The PCI score analysis showed a correlation between PCI score and non-radical surgery. The cause of severe perioperative complications was high malignancy (high grade), mesothelioma peritonei and metastases of gastric cancer. In the authors' opinion, in order to reduce the risk of non-radical resection and to limit severe perioperative complications, at least 180 CRS/HIPEC procedures should be performed. In order to improve the oncologic treatment results, the early learning curve is 90 procedures according to the authors. After that, the 2-year survival rate increases. The authors highlight that such procedures should be performed in high-volume centers, which enables that the safety criteria can be met.

One of the earlier studies discussing the need of gaining experience in order to improve the surgical treatment outcomes in peritoneal metastasis patients was conducted in the Netherlands [12]. The study was conducted on 323 patients with peritoneal metastases of colorectal cancer (184 patients) or pseudomyxoma peritonei (139 patients) at three consecutive three-year intervals. CC-0 was 35.6%, 48.8%, 65.1% respectively. The differences between the intervals was statistically significant (p = 0.012). The postoperative complication rate dropped from 71.2% to 34.1% (P < 0.001). The hospital stay was reduced from 24 to 17 days between the second and third interval, while there was no difference between the first and second interval. The two-year survival increased from 59.7% in Interval 1 to 61.9% in Interval 2 and further to 71.7% in Interval 3. The authors established that the improved results in terms of CC-0 were reached after 130 procedures.

The opinions on beneficial and necessary monitoring by a more experienced facility over a center beginning to perform cytoreductive surgery was presented in the study by Kusamua et al. [13]. The cooperation by mentoring allows to shorten the learning curve for CRS/HIPER and limit the initial risk factors such as inaccurate qualification, qualifying patients with overly advanced disease relative to the surgeon's experience, which may lead to incomplete cytoreduction, severe perioperative complication and high perioperative mortality rate. This opinion was presented by the Italian researchers from one of the most experienced centers in surgical treatment of peritoneal metastases [14]. The study was conducted on 420 patients with peritoneal cancer undergoing CRS/HIPEC. The analysis cover the rate of incomplete cytoreduction, severe postoperative complications and perioperative mortality. The risk factors for incomplete cytoreduction in multifactorial analysis included: compromised general condition

Tab. I. Opinions by the European experts in peritoneal cancer treatment with CRS/HIPEC.

SOURCE (EXPERT)	*LEARNING CURVE*	*HIGH- VOLUME CENTER*	SURGICAL TEAM'S EXPERIENCE	TRAINING PROGRAM	COOPERATION WITH MENTORS	DATABASE
Prof. B. Rau		Yes	Yes		Yes	Yes
Prof. M. Deraco	150 procedures	Yes	25 procedures per year		Yes	
Prof. O. Glehen			20–30 procedures per year	Yes	Yes	
Prof. V. Verwaal	100 procedures	Yes		Yes	Yes	

(P = 0.01), PCI > 20 points (P = 0.001), previous systemic chemotherapy (P = 0.011), histological type (P = 0.027) and experience gain evaluated in consecutive 50-patient groups (P = 0.042). The risk factors for sever perioperative complications in multifactorial analyses were age (> 52 vs < 52; P = 0.009), low albumin level < 3.5 g/dL (P = 0.019), PCI > 20 points (pp = 0.002), surgery duration > 600 min vs < 600 min (P = 0.025). The complication rate was not affected by the experience expressed by the number of performed CRS/HIPEC procedures, which can be explained by limitation of complication rate after 140 procedures. The authors stated that this number of CRS/HIPEC procedures allows to achieve the optimal results in terms of complete cytoreduction and reduced complication rate.

Huang et al. [15] presented the result of their study on a group of 800 patients undergoing CRS/HIPEC for primary and secondary peritoneal cancer. The patients were divided into eight groups of 100 patients. The analysis showed improvement in terms of five-year survival between group 1 (the first 100 patients) and group 4 (patients 301 – 400). For colorectal cancer metastasis the survival rate was 15% vs 31% respectively, for PMP – 64% vs 94% respectively, and for mesothelioma – 40% vs 52% respectively. The improved outcomes were also observed in terms of reduced perioperative complication rate, reduced need for blood transfusion and shorter hospital stay. The authors point out that the improved outcomes were achieved after 200 CRS/HIPEC procedures. Also, treatment was limited in patients with advanced peritoneal metastases from PCI < 20 points to PCI < 15 points.

Kuijpers et al. also studied the issue of the influence of the learning curve on the therapeutic outcomes in patients with peritoneal metastases. They compared the treatment outcomes of 372 patients with peritoneal metastases undergoing CRS/HIPEC in the experienced center and in the new center providing cytoreduction surgery. Mentoring by the experienced center had a positive influence on the initial rate of complete cytoreduction in the new center, which was 86% compared to 66% for the first 100 procedures in the mentoring center (P < 0.001). The mentoring also caused limitation of severe perioperative complications compared to the pioneering center. The authors believe that mentoring allows to reduce the learning curve, improve early quality of cytoreduction surgery and reduce perioperative complications.

OPINIONS OF EXPERTS FROM THE MOST EXPERIENCED CLINICAL CENTERS IN CYTOREDUCTIVE SURGERY AND HIPEC

The literature review on the requirements which should be met by the surgeon performing CRS/HIPEC showed diverse recommendations regarding experience necessary for optimal outcomes and reduced perioperative complication rate. The number of procedures lies between 40 and 90 and often depends on the number of procedures performed in the particular center. The experience of the center, in turn, should be no less than 90 procedures (up to 200) in order to recognize the center as meeting the criteria. Considering the effect of cooperation between more and less experienced centers on reducing the number of independent ('early') cytoreductive procedures by the surgeon and on the experience of the entire center, the learning curve is not standardized and depends on many factors.

In order to obtain reliable expert opinion, we sent e-mails to the recognized European experts in peritoneal cancer treatment with CRS/HIPEC, namely to:

1. Prof. Beate Rau, Chirurgische Klinik Campus Charite Mitte, Berlin, Germany;
2. Prof. Marcello Deraco, Director of the Peritoneal Surface Malignancies Unit Fondazione IRCCS Istituto Nazionale deiTumori: via Venezian, 1, 20133 Milano, Italy, Co-Director of ESPSO European School for Peritoneal Surface Oncology;
3. Prof. Olivier Glehen, Service de chirurgie digestive et endicrinienne, Centre Hospitalie Lyon Sud, France;
4. Prof. Vic Verwaal, Aarhus University Hospital, Denmark.

According to the expert opinions presented in Tab. I., the minimum of 100 to 150 procedures performed at a center is necessary for the optimal quality of cytoreductive surgery and therapeutic outcomes of CRS/HIPEC. Three experts highlighted the need of performing such procedures at a high-volume center. The experience of the whole team is necessary, which required the minimum of 25 or 20 to 30 procedures annually. Two experts pointed out the need of training programs in CRS/HIPEC for surgeons, and all experts indicated cooperation with mentoring centers as an element necessary to achieve the best results by new centers. One expert highlighted the need of implementing a database for constant analysis of treatment outcomes. Such databases are implemented in German, French and Dutch centers.

PROPOSED ACCREDITATION RECOMMENDATIONS BY THE ASSOCIATION OF POLISH SURGEONS AND THE POLISH SOCIETY OF SURGICAL ONCOLOGY REGARDING THE MINIMUM REQUIREMENTS FOR A REFERENCE CENTER

Based on the literature review, our own experience and consultation with international experts, the Surgical Team of the Peritoneal Cancer Section of the Polish Society of Surgical Oncology developed a model of fundamental requirements for clinical centers needed to be recognized as the Reference Center (authorizing procedures) as shown in Tab. II.

During the development of specialist peritoneal cancer centers combining surgical intervention with intraoperative chemotherapy,

Tab. II. Accreditation Requirements by the APS and PSSO for centers providing cytoreductive surgery and HIPEC for primary and secondary peritoneal cancer.

NO	ACCREDITATION REQUIREMENTS
1.	The hospital provides full range of abdominal surgeries
2.	The postoperative intensive care unit is accessible in the postoperative period following CRS/HIPEC
3.	The hospital infrastructure enables preparation, administration and utilization of cytotoxic drugs
4.	The staff is experienced in managing patients undergoing chemotherapy
5.	The surgical team providing CRS/HIPEC is experienced in extensive oncologic abdominal surgeries
6.	The surgical team is dedicated to CRS/HIPEC
7.	The operator's experience is > 50 CRS CC-0/1 (Reference Center) or < 0 CRS CC-0/1 (the center cooperating with the mentoring Refence Center for CRS/HIPEC evaluation
8.	Minimum of 20–25 CRS/HIPEC performed annually
9.	Obligatory registration of all CRS/HIPEC procedures in the CRS/HIPEC Procedure Registry
10.	Obligatory annual analysis of CRS/HIPEC procedures based on the Registry data

it is crucial to present the Procedure Leader, who should be a specialist in general surgery and/or surgical oncology. Such a person should be experienced in peritoneal cancer management and abdominal surgery. Additionally, the surgical treatment outcomes will be assessed annually considering cytoreductive surgery and HIPEC, which is meant to provide adequate quality of surgical interventions, which are the mainstay of cancer treatment. Moreover, it will be necessary to have a certificate of training in using HIPEC equipment.

IMPLEMENTATION OF THE ACCREDITATION PROCESS FOR CRS/HIPEC CLINICAL CENTERS BY THE ASSOCIATION OF POLISH SURGEONS AND THE POLISH SOCIETY OF SURGICAL ONCOLOGY

In order to develop the accreditation standards, the Peritoneal Cancer Section of the APS issued a request to the Board of the APS and the Board of the PSSO to consider the proposed requirements for clinical centers and surgical teams, which should be met for the best management of peritoneal cancer patients. The proposal was presented and discussed twice during meetings attended by surgeons performing CRS/HIPEC and experienced in extensive abdominal surgeries. Additionally, everyone interested could express their opinions and conclusions through e-mails. Later, after obtaining the acceptance by the National Consultant for General Surgery and the National Consultant for Surgical Oncology, we requested the Boards of the APS and PSSO to establish a joint committee to evaluate whether clinical centers meet the accreditation requirements. Both ASP and PSSO assigned two representatives each, who were experienced in CRS/HIPEC and/or extensive abdominal surgeries.

After obtaining the acceptance of the Accreditation Committee, the centers were registered in the CRS/HIPEC Procedure Registry and will be subject to systematic professional evaluation in terms of therapeutic outcomes in peritoneal cancer patients. The less experienced centers (no or less CRS/HIPEC procedures than is required for accreditation) are obliged to choose a reference center meeting all accreditation requirements for later cooperation. Is it in accordance with international expert opinions and literature data. The Accreditation Committee will annually analyze the quality of cytoreductive surgery in terms of patient qualification and surgical procedure quality based on the data from the CRS/HIPEC Procedure Registry. All patients undergoing CRS/HIPS must be registered, which is one of the accreditation requirements.

This paper has been written by the Peritoneal Cancer Section of the Polish Society of Surgical Oncology, which is actively cooperating with the Association of Polish Surgeons. It will be published in journals of both associations at the same time, i.e. in *The Polish Surgical Review* and *Cancer. Journal of Oncology*.

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